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DEPARTMENT OF CHEMISTRY IRVINE, CALIFORNIA 92697-2025

December 12, 1996

Mr. John D. Dunlap, III
Chairman
Air Resources Board
2020 L Street
Sacramento, California 95618

Dear Chairman Dunlap:

I am pleased to forward to you the Scientific Review Panel's (SRP/Panel) Findings (enclosure) for the Report on Inorganic Lead as adopted unanimously at the Panel's October 31, 1996 meeting.

The data in the scientific risk assessment on exposure to lead (Part A) and its health effects (Part B) developed and reviewed by OEHHA and the ARB are extensive and scientifically sound. Our Findings emphasize the fact that neurodevelopment effects in children and cardiovascular effects in adults are the major concerns for public health.

The approximately 20-year old federal standard of 1.5 micrograms per cubic meter of outside ambient air was based on preventing blood lead levels in 99.5% of children from exceeding 30 micrograms per deciliter. Clearly, the existing air quality standard is much too high in light of the most recent Centers for Disease Control (CDC) findings establishing a level of 10 micrograms per deciliter as a "level of concern." (This is pointed out in our Findings.)

As a result of the ARB actions (e.g. requiring strict automotive emission standards and the removal of lead from gasoline from the mid 1970's to 1992), there has been a significant reduction of respirable lead in ambient airborne particles in California. However, even at the 1990-91 population-weighted ambient lead concentration in California of 0.06 micrograms per cubic meter, the additional number of children age one and two with blood lead levels above 10 micrograms per deciliter is estimated to range between 7,200 and 27,600. According to the CDC, a blood lead level above 10 micrograms per deciliter has significant neurological implications for children.

Furthermore (see Finding No. 7), the number of deaths among adults 40 to 59 related to an increase in diastolic blood pressure associated with an increase in airborne lead concentrations from zero to 0.06 micrograms per cubic meter is estimated to range from 9 to 218 deaths per year over a 19 year period. Given the overall health impacts of lead from exposure through multi-media sources, the ambient airborne lead at current levels adds relatively little lead exposure when compared with all other sources. Nevertheless, the health impacts of ambient airborne lead are important. Moreover, toxic hot spots pose significant risks.

The Panel understands it does not have a mandated responsibility to address Risk Management. However, inorganic lead is one of the more detrimental and potent toxic air contaminants reviewed by the SRP, particularly because of neurodevelopmental and cardiovascular toxicity. This is the first compound to be addressed by the Air Resources Board where the overriding concern is the neurodevelopmental effects and cardiovascular mortality rather than the risk of cancer Thus, in this specific instance, we felt the SRP would be remiss in its responsibility as an advisor to the ARB if it did not point out the substantive issues that make exposure to lead a very significant, contemporary public health issue. For example, when one considers current exposure to inorganic airborne lead, including near sources, relative to its ambient air quality standard in conjunction with its unit risk of noncancer effects, this ubiquitous environmental pollutant remains among the more important toxic air contaminants of concern. The overall noncancer adverse health impacts from exposure to lead from a variety of sources (e.g. paint, soil, water, and air to a smaller extent) are significant. Indeed, the Panel's concern for general public health for lead exposure from all sources actually exceeds our level of concern for many of the toxic air contaminants this Panel has already reviewed over the last decade.

We recognize the importance and challenge that will be faced by the ARB and the local air pollution districts in developing a risk management program to reduce further the public exposure to inorganic lead particles, particularly with regard to toxic hot spots. We want to stress that our evaluation of the information presented by ARB and OEHHA staff in this document strongly implies that any increase in current exposure levels to airborne lead particles should be prevented. We believe that any risk management activities pursued by the ARB after inorganic lead is identified as a toxic air contaminant should make certain that airbornE lead exposure continues to decline below the current 0.06 micrograms per cubic meter statewide ambient average.

If additional information helpful to you is needed, we would welcome the opportunity to supply it.

Sincerely,

Dr. James N. Pitts
Chairman, Scientific Review Panel

Enclosure

cc: Scientific Review Panel Members

Michael Kenny, ARB
Bill Lockett, ARB

Findings of the Scientific Review Panel on
THE REPORT ON INORGANIC LEAD
as Adopted at the Panel's October 31, 1996 Meeting

Pursuant to Health and Safety Code section 39661, the Scientific Review Panel (SRP/Panel) has reviewed the report Proposed Identification of Inorganic Lead as a Toxic Air Contaminant by the staffs of the California Air Resources Board (ARB or Board) and the Office of Environmental Health Hazard Assessment (OEHHA) on the public exposure to, and health effects of, inorganic lead. The Panel members also reviewed the public comments received on this report. Based on this review, the SRP makes the following findings pursuant to Health and Safety Code section 39661:

1. Lead is known to cause significant noncancer health effects. The two noncancer health effects of most concern at low blood lead levels are neurodevelopmental effects in children, and increase in blood pressure and related cardiovascular effects in adults. The neurodevelopmental and cardiovascular effects likely have the most public health significance.

2. There is relatively little uncertainty in the risk assessments for the noncancer endpoints for lead, including neurodevelopmental and blood pressure effects compared to the cancer endpoint. Four major uncertainties associated with most risk assessments are animal-to-human extrapolation, high-to-low dose extrapolation, full consideration of sensitive members of the human population, and studies with small numbers of subjects. The uncertainty for the noncancer risk assessment for lead is small because it includes human and low dosage data, full consideration of sensitive members of the human population, and studies that contain numerous subjects.

3. Scientific studies have indicated that, at low to moderate blood lead levels, neurodevelopmental effects include: decreased intelligence, short term memory loss, reading and spelling underachievement, impairment of visual motor functioning, poor perception integration, disruptive classroom behavior, and impaired reaction time.

4. The data on the effects of lead on measures of intelligence are particularly compelling. Evidence from three prospective cohort studies show a relationship between blood lead levels and intelligence in children up to 10 years of age. The effects on intelligence appear to occur above and possibly below the 10 micrograms per deciliter "level of concern" identified by the Centers for Disease Control (CDC) and the National Academy of Sciences. A threshold for neurodevelopmental effects from lead exposure has not been identified. Based on scientific evidence for neurodevelopmental effects, an increase of 1 microgram per cubic meter of lead in ambient air inhaled would, on average, lead to a

decrease of approximately 1.32 intelligence quotient (IQ) points for children below the age of 10. Based on an evaluation of peer-reviewed evidence, it is estimated that there would be a mean decrease of 0.08 IQ points for children below the age of 10 exposed to the mean annual 1990-91 population-weighted exposure of 0.06 micrograms per cubic meter of airborne lead. While this effect may seem insignificant at the individual level, it would result in a downward shift in the distribution in IQ points for children in an exposed community. For example, at the ambient average air lead concentration of 0.06 micrograms per cubic meter, the models predict that 4,700 additional children in California have IQ levels below 80 relative to a zero air lead level.

5. Based on current scientific evidence and using blood lead data provided by the recent National Health and Nutrition Examination Survey (NHANES III), the percent of children that would move above the 10 micrograms per deciliter blood level of concern established by the CDC and accepted by OEHHA, can be calculated. The evidence suggests that at the mean annual 1990-91 statewide population-weighted air lead exposure of 0.06 micrograms per cubic meter, relative to a zero air lead level, an additional 0.6 to 2.3 percent of children between the ages of 1 and 2 could move above 10 micrograms per deciliter. This amounts to between 7,200 and 27,600 children in California. At an air lead concentration of 0.25 micrograms per cubic meter, the models indicate that an additional 5 to 13 percent of the children in this age group would move above 10 micrograms per deciliter.

6. Increases in both systolic and diastolic blood pressure and cardiovascular effects have been correlated with lead exposure. There are many large population-based studies that examine the relationship between blood lead levels and hypertension (diastolic blood pressure greater than or equal to 90 millimeters of mercury). In addition, scientific evidence indicates a consistent association between increases in blood pressure and increases in more serious cardiovascular outcomes.

7. Based on this evidence, exposure to the mean annual 1990-91 statewide population-weighted airborne lead exposure of 0.06 micrograms per cubic meter is estimated to lead to 26,000 (with a 95 percent confidence interval of 6,100 to 60,800) additional cases of hypertension (diastolic blood pressure greater than or equal to 90 millimeters of mercury) among the 7.92 million adults in California between the ages of 40 and 59. In addition, the exposure to 0.06 micrograms per cubic meter of air lead is estimated to result in 72 (with a 95 percent confidence interval of 12 to 164) fatal and non-fatal heart attacks per year and 74 (with a 95 percent confidence interval of 9 to 218) deaths from all cardiovascular related disease per year among the 8 million adults between the ages of 40 and 59. These values equate to a unit risk for mortality from cardiovascular disease of 4.6×10^{-4} per microgram per cubic meter (Table 1).

8. The risk assessment for potential near source exposure to inorganic lead at the annual average ambient concentration of 0.24 micrograms per cubic meter could result in a 4-fold increase in risk for neurodevelopmental effects, increased blood pressure and related cardiovascular effects, and cancer.

9. The current federal ambient air quality standard for lead developed by the United States Environmental Protection Agency (U.S. EPA) is 1.5 micrograms per cubic meter. This standard was based on preventing blood lead levels in 99.5 percent of children from exceeding 30 micrograms per deciliter, a level of concern that dates from 1978. The CDC has established a level of concern for children at blood lead levels of 10 micrograms per deciliter. At an air lead level of 1.5 micrograms per cubic meter, approximately one-half of California children would be expected to exceed the CDC guideline. Unfortunately, even if all airborne exposure to lead were eliminated, 10.9 percent of California children would exceed the CDC guideline of 10 micrograms per deciliter. With current air lead levels (0.06 micrograms per cubic meter), the percentage of children exceeding the CDC guideline of 10 micrograms per deciliter is anticipated to be 11.5 percent, 0.6 percent more children than if there were no lead in the air.

10. Lead compounds (which include organic and inorganic lead compounds) are listed as federal hazardous air pollutants (HAPs) and, therefore, were identified as toxic air contaminants (TACs) by the Board on April 8, 1993. However, the federal HAPs list does not include elemental lead in the definition of lead compounds. For this process, elemental lead is included in the ARB/OEHHA definition of inorganic lead and is, therefore, being considered for identification under the state's air toxics program.

11. The major sources of inorganic lead in ambient outdoor air are estimated to emit approximately 180 tons per year. Aircraft fuel combustion is the primary source of emissions at 149 tons per year. Other sources include autobody refinishing, battery manufacturing facilities, cement manufacturing, cogeneration, sawmills, paperboard mills, foundries and steel mills, stationary source fuel combustion, incineration, paint and coatings manufacturers, sand and gravel facilities, and secondary lead recycling facilities. Inorganic lead previously emitted from such sources may be re-entrained as windblown dust; ~~it~~ is expected to contribute 390 tons per year into the atmosphere. Ambient levels of inorganic lead can be much higher near sources which emit lead such as those listed above.

12. Based on air monitoring data collected by the ARB's criteria pollutant monitoring network, the 1990-91 statewide population-weighted exposure is estimated to be 0.06 micrograms per cubic meter. Current *statewide* population-weighted exposure is expected to be lower due to the ban on the use of leaded fuel for on-road vehicles in California effective January 1992, the implementation of a South Coast Air Quality Management District emission standard on lead (Rule 1420), and an air toxic control measure limiting lead emissions from stationary sources. The 1992-93 *near-source* annual average ambient concentration is 0.24 micrograms per cubic meter taken one third of a mile away from a specific secondary lead recycling facility.

13. Lead associated with particles may remain suspended in the atmosphere for up to 30 days. These particles are removed by wet and dry deposition.

14. Indoor concentrations are generally lower than outdoor concentrations; indoor/outdoor ratios range from 0.3:1 to 1:1.

15. Inhalation is not the only route of exposure to lead. Airborne lead that deposits on soil, water, and food can be ingested.

16. Most cases of lead poisoning in children are caused by ingestion of lead-based paint. Lead poisoning is also caused by the use of lead-containing traditional medicines from different cultures.

17. Scientific evidence suggests that a 1 microgram per cubic meter increase in atmospheric lead corresponds to 4.2 micrograms per deciliter (with a 95 percent confidence interval of 3.3 - 5.2 micrograms per deciliter) increase of blood lead over time for children and a 2 microgram per deciliter increase of blood lead for adults. The estimates have been developed using both an aggregate model and the U.S. EPA's Integrated Exposure Uptake Biokinetic Model (IEUBK) which incorporate the impacts of air lead emissions through all potential pathways.

18. California ambient air monitoring data from the mid 1970's to 1991 show a substantial decrease in ambient lead concentrations. This is primarily due to leaded fuel regulations that have eliminated the use of lead in automobile fuels and the introduction of catalyst equipped vehicles.

19. The International Agency for Research on Cancer (IARC) has listed lead and inorganic lead compounds in class 2B(1980), possibly carcinogenic to humans, based on sufficient animal carcinogenicity and inadequate human carcinogenicity data. The United States Environmental Protection Agency (U.S. EPA) has placed lead compounds in category B2(1986), probable human carcinogen, on the basis of sufficient evidence of carcinogenicity in animals, but inadequate or no data from human epidemiological studies.

20. Scientific studies show that lead can cause gene mutation and cell transformation in culture, and can interfere with DNA synthesis. Rodents that have ingested high doses of lead show increased occurrences of kidney tumors.

21. Based on a health protective interpretation of the available scientific information, the upper-bound of the lifetime excess unit cancer risk resulting from inorganic lead exposure ranges from 1.2×10^{-5} to 6.5×10^{-5} per microgram per cubic meter. This estimate of unit cancer risk was based on rodent data because there are inadequate data in humans. The best value for unit cancer risk is 1.2×10^{-5} per microgram per cubic meter, and is based on the largest data set available for quantitative assessment.

22. Based on the best value for potential unit cancer risk of 1.2×10^{-5} per microgram per cubic meter and the mean annual 1990-91 statewide population-weighted average of 0.06 micrograms per cubic meter, there could be 0.7 potential cancer cases per million people over a 70-year lifetime. Based on a population of 34 million California residents, the cancer burden is estimated to be 24 potential cancer cases.

23. Table 2, attached to these Findings, compares the best value of upper-bound unit cancer risk for inorganic lead with those of other compounds reviewed by the SRP. These 95 percent upper-bound lifetime risk estimates are health-protective estimates; the actual risk may be much lower.

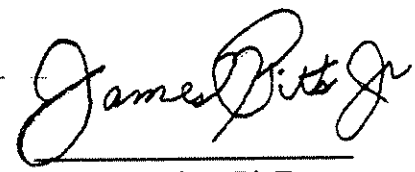
24. Based on available information, there is no evidence for a threshold for neurotoxicity, increased blood pressure and related cardiovascular effects, or cancer.

25. Based on available scientific evidence, we conclude that inorganic lead should be identified as a toxic air contaminant.

After careful review of the September 1996 draft SRP version of the ARB report, "Inorganic Lead as a Toxic Air Contaminant," we find this report with the changes specified in our October 31, 1996 meeting as representing a complete and balanced assessment of our current scientific understanding.

For these reasons, we agree with the science presented in Part A by ARB and Part B by OEHHA in the report on inorganic lead and the ARB staff recommendation to its Board that inorganic lead be listed by the ARB as a toxic air contaminant.

I certify that the above is a true and correct copy of the findings adopted by the Scientific Review Panel on October 31, 1996.



James N. Pitts, Ph.D.
Chairman, Scientific Review Panel

TABLE 1

NONCANCER POTENCIES APPROVED BY THE SCIENTIFIC REVIEW PANEL 1996

Compound	Unit Risk $(\mu g/m^3)^{-1}$	Endpoint
Inorganic Lead	**4.6×10^{-4}***	**Cardiovascular Mortality**

$\mu g/m^3$: microgram per cubic meter

* The noncancer risk is based on the predicted number of cardiovascular deaths for adults age 40 to 59. The estimate indicates an expected 74 deaths per year per 7.92 million California adults exposed to the 0.06 $\mu g/m^3$ airborne lead concentration. Therefore, the risk per $\mu g/m^3$ would be (74/7.92 million) x (1/0.06) = 1.56×10^{-4}. Using the upper 95 percent confidence estimate of 218 annual deaths for the 7.92 million California adults 40 to 59 generates a unit risk of 4.6×10^{-4}. These 95 percent upper-bound lifetime risk estimates are health-protective estimates; the actual risk may be much lower. (See Findings No. 7)

TABLE 2

CANCER POTENCIES APPROVED BY THE SCIENTIFIC REVIEW PANEL FROM 1984 TO 1996

(in order of cancer potency)

Compound	Unit Risk $(\mu g/m^3)^{-1}$	Unit Risk (ppbv)
Dioxins	3.8×10^{1}	Particulate Matter
Chromium VI	1.5×10^{-1}	Particulate Matter
Cadmium	4.2×10^{-3}	Particulate Matter
Inorganic Arsenic	3.3×10^{-3}	Particulate Matter
Benzo[a]pyrene	1.1×10^{-3}	Particulate Matter
Nickel	2.6×10^{-4}	Particulate Matter
1,3-Butadiene	1.7×10^{-4}	3.7×10^{-4}
Ethylene Oxide	8.8×10^{-5}	1.6×10^{-4}
Vinyl Chloride	7.8×10^{-5}	2.0×10^{-4}
Ethylene Dibromide	7.1×10^{-5}	5.5×10^{-4}
Carbon Tetrachloride	4.2×10^{-5}	2.6×10^{-4}
Benzene	2.9×10^{-5}	9.3×10^{-5}
Ethylene Dichloride	2.2×10^{-5}	8.9×10^{-5}
***Inorganic Lead**	**1.2×10^{-5}**	**Particulate Matter**
Perchloroethylene	5.9×10^{-6}	4.0×10^{-5}
Formaldehyde	6.0×10^{-6}	7.0×10^{-6}
Chloroform	5.3×10^{-6}	2.6×10^{-5}
Acetaldehyde	2.7×10^{-6}	4.8×10^{-6}
Trichloroethylene	2.0×10^{-6}	1.1×10^{-5}
Methylene Chloride	1.0×10^{-6}	3.5×10^{-6}
Asbestos	1.9×10^{-4} (per 100 fiber/m^3)	---

$\mu g/m^3$: microgram per cubic meter

ppbv: part per billion volume

*Noncancer deaths from exposure to Inorganic Lead are more significant than cancer effects (See **Table 1**).